Introduction to the Principles and Practice of Clinical Research (IPPCR)

October 19, 2009 – March 15, 2010

All sessions will meet on Monday and Tuesday evenings from 5:00 p.m. to approximately 6:30 p.m. (Eastern Standard Time) in the Lipsett Amphitheater.

Introduction	
Monday, October 19th Session 1	Welcome (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
	Unit 1: History of Clinical Research: A Merging of Diverse Cultures (30 minutes) John I. Gallin, M.D. Director, NIH Clinical Center
Module I, Statistical Methods	
Tuesday, October 20th Session 2	Unit 2: Participant Selection (45 minutes) Tamara Harris, M.D., M.S. Chief, Geriatric Epidemiology Section, NIA
	Unit 3: Using Secondary Data and Meta Analysis (45 minutes) Tamara Harris, M.D., M.S. Chief, Geriatric Epidemiology Section, NIA
Monday, October 26th Session 3	Unit 4: Design of Epidemiologic Studies (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, October 27th Session 4	Unit 5: Measures (1 hour) David Black, Ph.D. Psychologist Pediatric and Development Neuropsychiatry, NIMH Affairs, NCCAM
Monday, November 2nd Session 5	Unit 6: Designing and Testing Questionnaires Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Tuesday, November 3rd Session 6	Unit 7: Economic Analysis in Clinical Research (1.5 hours) **NO** lecture today. The 2008 video is on the course website.
Thursday, November 5th Session 7	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 9th Session 8	Unit 8: Issues in Randomization (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Tuesday, November 10th Session 9	Unit 9: Overview of Hypothesis Testing (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Thursday, November 12th Session 10	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D.

	Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 16th Session 11	Unit 10: Sample Size and Power (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 17th Session 12	Unit 11: Conceptual Approach to Survival Analysis (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Thursday, November 19th Session 13	Breakout Session – (1 hour) Title – TBD Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory Affairs, NCCAM
Monday, November 23rd	RECESS
Tuesday, November 24th	RECESS
Tuesday, November 30th Session 14	Unit 12: Ethical Principles in Clinical Research (45 minutes) Christine Grady, R.N., Ph.D. Head, Section on Human Subjects Research Bioethics Department, CC
	Unit 13: Research with Vulnerable Participants (45 minutes) David Wendler, Ph.D. Head, Unit on Vulnerable Populations Section on Human Subjects Research, Clinical Bioethics Department, CC
Tuesday, December 1st Session 15	Unit 14: Efficient Clinical Trials Dr. John Powers, III, M.D. Senior Medical Scientist, NCI-Frederick
Monday, December 7th Session 16	Unit 15: Study Development (1.5 hours) Laura Lee Johnson, Ph.D. Statistician, Office of Clinical and Regulatory
Module II, Ethical Issues and Regulation of Human Subjects Research	
Tuesday, December 8th Session 17	Unit 1: Legal Issues in Clinical Research (1 hour) Valerie Bonham, J.D. Senior Attorney, Office of General Counsel, NIH
Monday, December 14th Session 18	Unit 2: Concepts in the Management of Projects (1 hour) Christopher Breder, M.D., Ph.D. Medical Officer, Center for Drug Evaluation and Research, FDA
Tuesday, December 15th Session 19	Unit 3: Evaluation of a Protocol Budget (1.5 hours) Margaret Matula, R.N., B.S.N., M.G.A. Director, Research and Clinical Trials Anne Arundel Medical Center
Monday, December 21st	RECESS
Tuesday, December 22nd	RECESS
Monday, December 28th	RECESS
Tuesday, December 29th	RECESS
Monday, January 4th	Unit 4: Special Lecture:

Session 20	Human Genome Project and Clinical Research (1 hour) Christopher Austin, M.D. Senior Advisor to the Director for Translation Research, NHGRI
Tuesday, January 5th Session 21	**Breakout Session:** Mock IRB (2 hours) Jerry Menikoff, M.D., J.D. Director, Office of Human Research Protections Office of Public Health and Science, DHHS
Monday, January 11th Session 22	Unit 5: Data and Safety Monitoring Boards (1 hour) Dennis O. Dixon, Ph.D. Mathematical Statistician Biostatistics Research Branch, NIAID
Tuesday, January 12th Session 23	Unit 6: The Clinical Researcher and the Media (45 minutes) John Burklow, M.S. Associate Director for Communications Office of Communications and Public Liaison, NIH
	Unit 7: Product Development: Moving from the Bench to the Clinic (45 minutes) Richard Schwartz, Ph.D. Chief, Vaccine Production Program Lab Vaccine Research Center/NIAID/NIH
Monday, January 18th	FEDERAL HOLIDAY
Tuesday, January 19th Session 24	Unit 8: FDA Product Regulation (1.25 hours) Robert Yetter, Ph.D. Associate Director for Review Management Center for Biologics Evaluation and Research, FDA
Module III, Monitoring Patient-Oriented Research and Regulatory Issues	
Monday, January 25th Session 25	Unit 1: Data Management in Clinical Trials (1 hour) Diane St. Germain, R.N., M.S., C.R.N.P. Nurse Consultant Division of Cancer Prevention, NCI
Tuesday, January 26th Session 26	Unit 2: Quality Control in Clinical Trials (1 hour) Jack Guralnik, M.D., Ph.D. Chief, Epidemiology and Demography Section, NIA
Monday, February 1st Session 27	Unit 3: Quality of Life (1 hour) John Ware, Ph.D. CEO and Chief Science Officer, QualityMetric, Inc
Tuesday, February 2nd Session 28	Unit 4: Scientific Conduct (45 minutes) Joan Schwartz, Ph.D. Assistant Director Office of Intramural Research, NIH
Monday, February 8th Session 29	Unit 5: NIH Peer Review Process (1 hour) Olivia Bartlett, Ph.D. Chief, Research Programs Review, NCI
Module lV, Preparing and Funding a Clinical Research Study	

Tuesday, February 9th Session 30	Unit 1: Information Resources for Clinical Research (1 hour) Josh Duberman, M.L.I.S. Informationist/Research Librarian
Monday, February 15th	FEDERAL HOLIDAY
Tuesday, February 16th Session 31	Unit 2: Clinical Research from the Patient's Perspective (1 hour) Susan Butler, B.A., M.A. Vice President, Ovarian Cancer National Alliance
Monday, February 22nd Session 32	Unit 3: Design of Case Report Forms (1 hour) David Mailhot, B.S., M.P.H. Director, Global Research and Development Global Clinical Data Services Pfizer Global Research and Development
Tuesday, February 23rd Session 33	Unit 4: ProtoType and Protocol Mechanics (1 hour) Philip Lightfoot, B.S., B.A. Systems Analysis, DCRI, CC
Monday, March 1st Session 34	Unit 5: Technology Transfer (1.5 hours) Bruce Goldstein, J.D. Unit Coordinator, Technology Transfer Branch, NCI
Tuesday, March 2nd Session 35	Unit 6: Inclusion of Women and Minorities in Clinical Trials (1 hour) Miriam Kelty, Ph.D. Former Associate Director, Extramural Activities, NIA
Monday, March 8th Session 36	Unit 7: Evaluation of Alternative and Complementary Therapies (1 hour) Marc Blackman, M.D. Associate Chief of Staff for Research and Development Veteran's Administration Medical Center
Tuesday, March 9th Session 37	Unit 8: Health Disparities Research Kyu Rhee, M.D., M.P.P., FAAP, FACP Director, Office of Innovation and Program Coordination, NCMHD
Monday, March 15th Session 38	Unit 9: Community-Based Participatory Research Francisco Sy, M.D., DrPH Director, Division of Extramural Activities & Science Programs National Center for on Minority Health & Health Disparities, NIH

*Schedule subject to change